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OBJECTIVES: Infliximab is indicated in Crohn's disease (CD) resistant to standard treatment (ST), but its impact on health care costs and quality-adjusted life-expectancy is incompletely understood. We assessed the cost-effectiveness of episodic (ET) and maintenance (MT) infliximab treatment in CD patients with 10-years follow-up. **METHODS:** A total of 212 incident adult CD patients (age at onset 34.4±14.5 years, 49.4% male) were treated with antibiotics, mesalazine, corticosteroids, thiopurines, surgery (comprising ST) over 10-years to 2004. Eight health states were defined by intensity of therapy in these patients. We determined Markov transition probabilities between these states, health care costs and QALYs in 3 month-cycles. This cohort was modeled to allow drug-refractory or pre-surgery patients to receive infliximab: either ET in one cycle, or MT in responders for a period of 1-year (MT-1yr) or for 10-years (MT-10 yrs). Transition probabilities of ST were applied to patients getting IFX; the probability of continuing infliximab in MT was set to correct for decay. Health care costs and QALYs in ET and MT were estimated for 10-years (discounted at 3%) and compared with those of ST patients. **RESULTS:** The average cost (QALYs gained) per patient over 10-years was €23,169 (6.7014) for ST; €21,691 (7.0403) for ET, €29,012 (7.0553) for MT-1yr, and €50,416 (7.2603) for MT-10 yrs. ST was associated with higher costs and lower outcomes and was thus dominated by ET. The incremental cost-effectiveness ratios (ICERs) of MT-1yr and MT-10 yrs over ST were €16,510/QALY gained, and €48,751/QALY gained, respectively. When compared with ET, the ICERs of MT-1yr and MT-10 yrs were €488,066/QALY gained, and €130,568/QALY gained, respectively. When the infliximab price was halved these ICERs remained very high. **CONCLUSIONS:** ET or MT with infliximab are either cost-saving or cost-effective when compared with ST. However, at current drug prices, MT does not provide good value for money when compared with ET.

PGI24

COST-EFFECTIVENESS ANALYSIS OF 48-WEEK PEGINTERFERON ALPHA-2A UNDER RGT STRATEGY VERSUS 3 YEARS ENTECAVIR FOR THE TREATMENT OF HBEAG-POSITIVE CHRONIC HEPATITIS B IN CHINA

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OBJECTIVES: To evaluate direct medical costs, health outcomes, and cost-effectiveness of 48-week Peginterferon alpha-2a with 2nd line 2-years Entecavir treatment versus 3 years Entecavir treatment for HBeAg-positive chronic hepatitis B according to the Response Guided Treatment (RGT) strategy in China. **METHODS:** A Markov model was designed to evaluate the direct medical costs and outcomes (life years and QALYs gained) of treating HBeAg-positive chronic hepatitis B in China, with a maximum analysis time horizon of 80 years. The model included 10 health states – Chronic hepatitis B (CHB), HBeAg seroconversion, HBsAg loss, CHB with resistance, Compensated cirrhosis, Decompensated cirrhosis, Hepatocellular carcinoma, Liver transplant, Post-liver transplant and death. Based on the analysis of published literature, a two-round expert panel survey was conducted among 22 hepatitis B specialists nationally to identify clinical and utility data. From the perspective of China's health insurance system, cost data was calculated based on the published literature about CHB economic burden. A discounting rate at 3% was used to discount medical costs and health outcomes that happened at different years. A univariate sensitivity analysis was performed to understand the key drivers and general sensitivity of the model. **RESULTS:** The model results showed that the utilization of Peginterferon regimen can prolong1.80 QALYs (15.00 years vs. 13.20 years), compared to the 3 years Entecavir treatment. The total cost per patient treated with Peginterferon and Entecavir was RMB 163,638 yuan (US$ 25,568) and RMB 145,116 yuan (US$ 22,674), respectively. The discounted incremental cost per QALY gained for Peginterferon regimen was RMB 10,298 yuan (US$ 1,609) (Exchange rate: 1 US$ = 6.4 CNY). **CONCLUSIONS:** The results of the model suggest that 48-week Peginterferon alpha-2a with 2-years Entecavir treatment as 2nd line improves health outcomes in a cost-effective manner compared with 3 years Entecavir for the treatment of HBeAg-positive chronic hepatitis B in China.

PGI25

COST-UTILITY ANALYSIS OF TELAPREVIR IN COMBINATION WITH PEGINTERFERON ALPHA AND RIBAVIRIN IN PREVIOUSLY TREATED PATIENTS WITH CHRONIC HEPATITIS C

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OBJECTIVES: To estimate the cost-effectiveness of telaprevir in combination with peginterferon alpha and ribavirin (PR) compared to PR alone in previously treated patients. **METHODS:** A cost-utility analysis based on previously published Markov models for chronic hepatitis C was used. Efficacy in the model was derived from results of randomized placebo controlled trial (REALIZE). REALIZE compared telaprevir in combination with PR to PR alone in patients who failed previous treatment. The trial showed significantly higher response rates in the telaprevir patient cohort. Utility values corresponding to each health state in the model were obtained from a NICE Health technology Assessment and were combined with data from REALIZE. Local cost data sources were from published price lists, clinical guidelines, product labels and expert opinion (DELPHI panel). The effectiveness was measured in quality-adjusted life years (QALY). Time horizon was set at lifelong (100 years of age or till patient dies) and a payers' perspective was adopted. Discount rate was 5% per year for both costs and effects according to actual Ministry of Health guidelines for health economic evaluation. Both one-way and probabilistic sensitivity analyses were performed. **RESULTS:** Incremental cost effectiveness ratio (ICER) for telaprevir in combination with PR compared to PR alone was 14 209 €/1 QALY. Costs for one life year saved (LYS) were 20 026 €/1 LYS. Model was most sensitive to price of telaprevir in deterministic sensitivity analysis. In probabilistic sensitivity analysis 75 % of simulations were below 26 650 €/1 QALY. **CONCLUSIONS:** Telaprevir in combination with PR is a cost-effective compared to PR alone for the treatment of chronic hepatitis C in patient who failed previous treatment with PR in a Slovakian health care system.

PGI26

WITHIN-TRIAL ANALYSIS TO ESTIMATE THE ECONOMICALLY JUSTIFIABLE PRICE OF LINACLOTIDE IN THE TREATMENT OF IRRITABLE BOWEL SYNDROME WITH CONSTIPATION IN THE UK

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OBJECTIVES: Linaclotide is a novel once daily, orally delivered peptide that acts on all key IBS-C symptoms. The aim of this analysis was to estimate the daily cost that would result in linaclotide being considered cost-effective in the UK, given different levels of willingness–to-pay (WTP). **METHODS:** A within-trial analysis was used to estimate the economically justifiable price from a payer perspective in the UK using patient-level data from a 26-week Phase III, randomized, double-blind trial of linaclotide 290μg daily (n=401) versus placebo (n=403) in IBS-C patients (modified Rome II criteria). EQ-5D data was collected at randomization and each subsequent visit. The UK valuation of the EQ-5D was applied to the raw data to estimate the utility for each patient. Missing data were interpolated using the last-observation-carried-forward (LOCF) method. The WTP was varied from £15,000-£20,000/QALY. The only cost considered was that of linaclotide; total cost of treatment was weighted by compliance. Resource use was assumed to be equal between arms. Bootstrapping was performed to account for uncertainty. A scenario analysis was conducted using data from a 12-week linaclotide trial in a similar population. **RESULTS:** Patients treated with linaclotide gained 0.016 QALYs over the 26-week trial compared with patients in the placebo arm. At WTP thresholds of £15,000-£20,000/QALY linaclotide could be cost-effective at a price of £1.30-£1.70. Over 75% of the bootstrap estimates fell below a willingness-to-pay threshold of £20,000/QALY. The method of addressing missing data had minimal impact on the ICER. In the scenario analysis, the QALY gain for patients treated with linaclotide was even greater, thus a price of £2.00-£2.65 may result in linaclotide being considered cost-effective at thresholds of £15,000-£20,000/QALY. **CONCLUSIONS:** The base case analysis showed linaclotide could be cost-effective at a price of up to £1.70/day in the UK setting using conservative assumptions.

PGI27

IMPACT OF LINACLOTIDE TREATMENT ON WORK PRODUCTIVITY AND ACTIVITY IMPAIRMENT IN ADULTS WITH IRRITABLE BOWEL SYNDROME WITH CONSTIPATION

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OBJECTIVES: Irritable bowel syndrome with constipation (IBS-C) can decrease work productivity and increase activity impairment, resulting in a substantial economic burden for patients and employers. Linaclotide, a minimally-absorbed guanylate cyclase C agonist (GCCA), significantly improved abdominal and bowel symptoms in 2 Phase 3 IBS-C trials. We evaluated the linaclotide treatment effect on work productivity and activity impairment in IBS-C patients. **METHODS:** In 2 Phase 3 trials, 1602 adults with IBS-C (modified Rome II criteria) were randomized to oral linaclotide 290 μg once daily or placebo. The self-administered 6-item Work Productivity and Activity Impairment questionnaire for IBS-C (WPAI:IBS-C) was used to evaluate IBS-C symptom-related absenteeism (work hours missed), presenteeism (degree symptoms affected work productivity), overall work productivity loss (absenteeism+presenteeism) and daily activity impairment (degree symptoms affected activities) over the previous week. Using pooled intent-to-treat data, changes in WPAI:IBS-C scores from baseline to Weeks 4, 8, and 12 were assessed by analysis of covariance and represented as percentages (higher percentage=greater productivity loss and activity impairment). Absenteeism, presenteeism and work productivity assessments included employed patients only. **RESULTS:** Compared to placebo, linaclotide significantly reduced presenteeism, overall work productivity loss and daily activity impairment, and numerically decreased absenteeism, at Weeks 4, 8 and 12. Mean changes from baseline to Week-12 for linaclotide and placebo, and the corresponding treatment effect (LS-means difference between linaclotide and placebo, shown as "Δ"), respectively, were: presenteeism, -18.4% and -13.1% (Δ=-5.2, P<0.0001); overall work productivity loss, -19.4% and -13.0% (Δ=-6.1, P<0.0001); daily activity impairment, -19.9% and -15.2%(Δ=-4.7, P<0.0001); absenteeism, -1.6% and -0.9% (Δ=-0.5, P=0.311). Assuming a 40-hour work week, linaclotide reduced overall work productivity loss by 1.6-2.4 hours/week. **CONCLUSIONS:** Linaclotide significantly reduced presenteeism, overall work productivity loss and daily activity impairment for IBS-C patients